



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/680,950 | 10/08/2003 | Robert W. Langley | 96-03 | 6033 |
| 23713 | 7590 | 09/12/2006 | EXAMINER | |
| GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301 | | | DEAK, LESLIE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/680,950 | ANGLEY ET AL. |
| | Examiner | Art Unit |
| | Leslie R. Deak | 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-68 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 October 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/17/04, 4/5/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. In response to the election of Species Requirement mailed on 1 June 2006, Applicant argues that all the claims read on the elected species and that the instantly presented claims are similar enough to be examined together. Examiner has grouped the claims together and treated them as similar inventions, as suggested by applicant.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 55 attempts to quantify a variable flow by reciting a quasi-steady state flow "constant to within 10%." However, applicant fails to elucidate what type of flow remains constant: volumetric flow, rate of flow, flow pressure, or any other such measurement of flow conditions. Accordingly, examiner has assumed that 10% pertains to volumetric flow through the system and has treated the claim on its merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 11, 12, 14-15, 17-22, 25-27, 40, 42-45, 47-50, 67 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,179,801 to Holmes et al.

In the specification and figures, Homes discloses the method claimed by applicant. With regard to claims 25-27, Holmes discloses a blood processing apparatus and method that comprises the steps of entering patient data into a control screen to calculate the donor's total blood volume and using the total blood volume in the determination of various parameters of the apheresis procedure (see column 56, lines 61 to column 57, line 2). Holmes specifically discloses that blood inlet pump 1030 is operated according to parameters stored in blood component separation device 6, which receives the patient parameters described above (see column 27, lines 15-25). Therefore, the removal of blood from the patient via removal pump 1030 is performed in a manner derived from the predetermined operating protocol stored in apheresis machine 6, which operates, in part, on patient blood volume data. Similarly, Homes discloses that the return rate of the blood return submode via return pump 1090 is established by blood component separation device 6 according to a predetermined protocol (see column 27, lines 15-25). As such, Holmes discloses the method claimed by applicant, meeting the limitations of the claims.

With regard to applicant's claims drawn to "systematic" variance of flow rates (eg, claims 1, 23), Holmes clearly discloses that the apheresis system 6 varies the flow rates based on a predetermined operating scheme (see column 27, lines 15-25, column 56,

lines 60-67). Since the system controls such variations, Examiner considers flow rates adjusted by the apheresis system 6, including elimination of flow at the end of the processing period (see column 28, lines 40-44) to correspond to applicant's "systematic" variations, since the variations are derived from the system

With regard to claims 12, 40, and 67, Holmes specifically discloses that blood is removed and returned through patient access 30 and needle 32 (see FIG 2A).

With regard to claims 42, 43, 21, and 22, Holmes discloses that the blood processing method includes a blood removal submode and a blood return submode that repeat sequentially for a predetermined amount of time (see column 28, lines 40-44).

With regard to claims 44, 45, 14, and 15, Holmes specifically discloses that the blood processing procedure may be used to separate a patient's whole blood via a centrifuge into constituent components, wherein one or more components are retained by the system (corresponding to applicant's claimed collect component) and the undesired components are returned to the patient (see column 1, lines 16-25; see also column 8, lines 20-60 for density centrifuge).

With regard to claims 47-50 and 17-20, Holmes discloses that the collected component may comprise red blood cells, white blood cells, platelets, or plasma (see column 1, lines 16-25).

With regard to claim 1, Holmes discloses that the return pump 1090 may be started and stopped according to the operating parameters of the system, thereby varying the rate of fluid return to the patient (see column 27, lines 25-35).

Art Unit: 3761

With regard to claim 2, Holmes discloses that the return pump 1090 is stopped after the completion of the return time (see, for example, column 28, lines 40-43). Such a stoppage represents a decrease in the return flow rate, thereby meeting the limitations of the claim.

With regard to claim 11, Holmes discloses that the blood removal submode may be stopped in response to signals from the blood separation device 6, thereby halting blood removal pump 1030 (see column 27, lines 10-15). Such stopping of the blood pump is considered by the examiner to vary the rate of the removal, meeting the limitations of the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-10, 23, 24, 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,179,801 to Holmes et al.

In the specification and figures, Holmes discloses the method substantially as claimed by applicant (see rejection above) with the exception of controlling the withdrawal and return rates in the specific manner claimed by applicant.

With regard to claims 3, 8, 9, and 10, Holmes specifically discloses in column 56, lines 61-67, that patient data such as patient blood volume are used to establish the

operating parameters of the apheresis device 6, thereby regulating the disclosed blood processing method. In column 27, lines 15-25, Holmes teaches that the volume transfer rate of blood flow is variable based on a “predetermined protocol” of the apheresis machine 6. Accordingly, this flow rate is regarded as a result-effective variable (see also at least column 28, lines 44-67 for discussion of variable flow rates). It has been held that the optimization of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, Examiner considers the flow rates claimed by applicant (eg, increasing, decreasing, exponentially decreasing, or linearly varying) to be a result-effective variable (the adjustment of which does not patentably distinguish over the prior art of record) that may be controlled by collected and calculated patient data, thereby meeting the limitations of the claims.

With regard to claims 4-7, 30-31, and 34-39, Applicant claims to establish a return flow rate based on a specific equation. As noted above, Holmes discloses that the flow rate is recognized to be a result-effective variable. These claims establish a method for setting/optimizing various flow rates via the selection of variable/optimal parameters. Absent a disclosure that applicant’s claimed equations provide a significant advantage over the prior art’s calculation, Examiner considers the selection of such variable parameters to be mere optimization of a result-effective variable through routine experimentation. Holmes specifically teaches that such parameters may be selected as desired by the operator and blood handling procedure (see, generally, columns 27-28). Accordingly, as previously noted, the optimization of a variable flow

rate is not considered to patentably distinguish applicant's invention from the prior art of record. See MPEP 2144.05.

With regard to claim 23, Holmes discloses that the blood removal submode may be stopped in response to signals from the blood separation device 6, thereby halting blood removal pump 1030 (see column 27, lines 10-15). Such stopping of the blood pump is considered by the examiner to vary the rate of the removal, meeting the limitations of the claims. With regard to applicant's claim limitation drawn to the ability of the method to reduce vessel infiltration, applicant discloses that such infiltration is generally a result of large pressure fluctuations while withdrawing or returning fluid to the patient's blood vessel. Holmes specifically discloses that pressure sensor 1200 senses negative and positive pressure changes in the removal tubing 22 and return tubing 26. The pressure signals are conveyed to the separation device 6, which controls the operation of removal pump 1030 and return pump 1090 (and thereby the flow rate) to maintain predetermined fluid pressures during the procedure (see column 27, lines 36-61). Holmes discloses that the pressure is controlled, which necessarily controls what applicant discloses is the cause of infiltration. It follows naturally that in controlling the pressure, the rate of infiltration is also controlled, thereby meeting the limitations of the claim.

With regard to claim 24, while increasing the removal flow rate is regarded as an optimization of a result-effective variable found in the prior art (see rejection above), Holmes specifically discloses that the blood processing method includes a blood

removal submode and a blood return submode that repeat sequentially for a predetermined amount of time (see column 28, lines 40-44).

With regard to claims 28 and 29, as previously noted, Holmes uses the total blood volume of the patient in the determination of various parameters of the apheresis procedure (see column 56, lines 61-67). Furthermore, Holmes appears to suggest that such parameters include the withdrawal and return flow rates (see, generally, columns 27-28). Therefore, the linear correlation of the flow rate and increase of the flow rate found in the claims would be a matter of optimizing a result-effective variable found in the prior art. It has been held that the optimization of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, Examiner considers the flow rates claimed by applicant (eg, increasing, decreasing, exponentially decreasing, or linearly varying) to be a result-effective variable (the adjustment of which does not patentably distinguish over the prior art of record) that may be controlled by collected and calculated patient data, thereby meeting the limitations of the claims.

With regard to claims 32 and 33, Applicant attempts to claim a method for determining blood volume with a formula based on patient sex, height, and weight. Holmes discloses that his procedure comprises a method for determining blood volume based on patient sex, height, and weight (see column 56, lines 48-67). Without a disclosure of how applicant's formula improves the determination of blood volume from that found in the prior art, Examiner considers the claimed formula to be merely a matter of optimizing the manner in which each procedure arrives at the patient's total blood volume. It has been held that the optimization of a result-effective variable involves only

Art Unit: 3761

routine skill in the art. See MPEP 2144.05. In the instant case, Examiner considers Applicant's selection of variable coefficients in an equation to be a matter of routine experimentation that optimizes accurate determination of patient blood volume.

8. Claims 13, 16, 41, 46, 51-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,179,801 to Holmes et al in view of US 6,730,054 to Pierce et al.

In the specification and figures, Holmes discloses the method substantially as claimed by applicant (see rejection above) with the exception of two needles to draw and return blood, an elutriation centrifugation, and a recirculation step.

With regard to claims 13 and 41, Pierce discloses a blood processing system that draws blood from a patient based on patient parameters such as patient blood volume, separates the blood into components, and returns the unused component to the patient (see column 1, lines 50-55, column 3, lines 57-63, column 12, lines 54-61). Pierce discloses that the system may comprise either a single needle blood collection system or a double needle system (see column 2, lines 65-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the blood processing procedure disclosed by Holmes with a two needles as disclosed by Pierce, since Pierce teaches that single and double needle processing systems are interchangeable.

With regard to claims 51 and 53, Pierce discloses a recirculation procedure that adds separated PRP to entering whole blood in order to maximize the separation of RBC and PRP to prevent contamination with RBC (see column 8, lines 54-65). As such, Pierce discloses the steps of conducting removed, anticoagulated WB through system

10, wherein the system collects RBC and PRP (see column 8, lines 29-32). The system collects a portion of the PRP for further processing (corresponding to applicant's first portion), and recirculates a portion of the PRP through the system to combine with WB for increased separation efficiency (wherein the recirculated PRP corresponds to applicant's claimed second portion) (see column 8, lines 29-60). During this mode, the controller returns unused RBC and PPP (corresponding to applicant's third component) to the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a recirculation step as disclosed by Pierce to the blood separation and collection procedure as disclosed by Holmes, in order to provide maximal separation of RBC and PRP, as taught by Pierce.

With regard to claims 16, 46, and 56, Pierce's recirculation of PRP into the collected WB creates a secondary elutriation process that increases the separation of platelets from WB by adding extra PRP as a washing fluid to provide maximal separation of RBC and PRP. Accordingly, Pierce discloses a blood separation procedure that uses both density centrifugation and elutriation to separate the desired blood components, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a washing/elutriation process as disclosed by Pierce in the blood processing procedure disclosed by Holmes, in order to increase separation efficiency, as taught by Pierce.

With regard to claim 52, Holmes discloses that the blood processing method includes a blood removal submode and a blood return submode that repeat sequentially for a predetermined amount of time (see column 28, lines 40-44).

With regard to claims 63-66, Holmes discloses that the collected component may comprise red blood cells, white blood cells, platelets, or plasma (see column 1, lines 16-25).

With regard to claims 54 and 55, Pierce is silent as to whether the system maintains steady-state flow. However, applicant merely claims “quasi” steady-state flow, which encompasses all states of flow that resemble a steady flow. Pierce discloses a blood processing system that recirculates a portion of PRP in a continuous fashion to the first stage of the processing chamber, creating a steady-state flow (column 8, lines 53-60). As such, the Pierce disclosure meets the limitations of the claims. With regard to applicant’s claim drawn to “constant within 10%,” examiner has assumed that this measurement pertains to volumetric flow. Pierce discloses that the entire volume of the recirculated fraction is reintroduced to the first stage of the separation vessel in a continuous fashion, meeting the limitations of the claim.

With regard to claims 57 and 58, the prior art discloses both a removed blood portion and a recirculated blood portion, each of which necessarily has a hematocrit value. This weighted average of the hematocrit values necessarily varies with the amount of blood supplied to the processing device. Pierce does not provide any limitation to the amount of fluid supplied to the recirculation loop, but does disclose that the amount is sufficient to establish desired conditions in the blood separation system. Therefore, Pierce suggests that the amount of recirculated portion may be selected to maximize a desired result—efficient separation of RBC and PRP. It has been held that the optimization of a result-effective variable involves only routine skill in the art. See

MPEP 2144.05. In the instant case, the portion of the recirculated flow is selected to provide the result of maximum separation of RBC and PRP.

With regard to claims 59-62 and 68, as noted above, each portion of blood necessarily has a hematocrit value, and the draw and return cycles each have a rate (see rejections above). Applicant uses an equation to set the duration of each cycle. Both Holmes and Pierce teach that the method comprises draw and return cycles. Broadly defined, a cycle comprises an interval of time (see Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001). All the values used in the determination of $F_{c\max}$ in the claimed equation are demonstrated by the prior art to be variable. It has been held that the optimization of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, the duration of the draw and return cycles are varied in order to provide a sufficient amount of time to provide blood to the separation system and to return components to the donor, respectively. (see Pierce, column 7, lines 45-50). Accordingly, absent a disclosure that applicant's claimed equations provide a significant advantage over the prior art's calculation of cycle duration, Examiner considers the selection of such variable parameters to be mere optimization of a result-effective variable through routine experimentation.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,637,082

Pages et al

i. Apheresis apparatus with patient parameter calculations

b. US 5,437,624

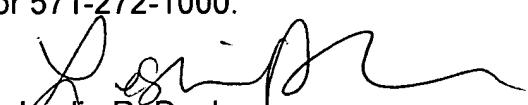
Langley

ii. Single needle recirculating apheresis apparatus

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
28 August 2006